Tapentadol Immediate-release Tablets (C-II)

Criteria for Use

September 2010

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services.

The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or http://vaww.pbm.va.gov for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive tapentadol.*

- ☐ Impaired pulmonary function (significant respiratory depression, acute or severe bronchial asthma, or hypercapnia in unmonitored settings or the absence of resuscitative equipment)
- ☐ Paralytic ileus
- ☐ Concomitant use or recent use (within 14 days) of monoamine oxidase inhibitors (MAOIs)
- ☐ Severe (Child-Pugh Class C) hepatic impairment or severe renal impairment
- ☐ Women during and immediately prior to labor and delivery
- ☐ Breastfeeding women
- ☐ Hypersensitivity to tapentadol or other opioids

Inclusion Criteria *The answers to all of the following must be fulfilled in order to meet criteria.*

- ☐ 18 years of age and older
- ☐ Able to take oral medications
- ☐ Moderate to severe ACUTE (e.g., postoperative) pain
- ☐ Contraindication, unmanageable intolerance, or inadequate analgesic response to all orally administered immediate-release / short-acting formulary opioid agents that are FDA-approved for moderate to severe pain; e.g., hydrocodone with acetaminophen, oxycodone with acetaminophen, hydromorphone, morphine, oxycodone, and tramadol.

Dosage and Administration

Refer to Product Information

Issues for Consideration

- Equianalgesic doses have not been established between tapentadol and any other opioids.
- The efficacy of tapentadol IR has not been evaluated beyond 10 days, and safety has not been evaluated beyond 90 days.
- Codeine with acetaminophen (60/1000 mg) and nonsteroidal analgesic drugs (such as the formulary agents diclofenac 50–100 mg, ibuprofen 200–400 mg; naproxen 400–550 mg; and piroxicam 20 mg) may be highly effective for moderate to severe postoperative pain with numbers needed to treat (NNTs) of less than 3 after single doses; however, they are FDA-approved for treatment of only mild to moderate pain.
- It is unclear whether patients who have had an inadequate analgesic response to hydromorphone, morphine, and oxycodone would be more likely to respond to tapentadol immediate-release.
- Tapentadol (50–200 mg) may have a lower risk of nausea, vomiting, and constipation than oxycodone 10–15 mg and morphine 60 mg but a higher risk of nausea and/or vomiting than ibuprofen 400 mg.

Prepared: September 2010. Contact: Francine Goodman, PharmD, BCPS, Clinical Pharmacy Specialist, VA Pharmacy Benefits Management Services

Formatted: Font: 14 pt

Formatted: Font: 14 pt